



April 28, 2005

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

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Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. 343 r (6) and in accordance with the authorized provisions of 21CFR 101.93, ADVOCARE provides notification for statements on dietary supplement labels as follows:

The name and address of the manufacturer, packer or distributor of the dietary supplement that bears the statements:

ADVOCARE International, L.P.
2727 Realty Road
Carrollton, TX 75006

Product Name: OmegaPlex

Statement(s)

Basis for Statement(s)

The omega-3 fatty acids in OmegaPlex are involved in the following functions: Eicosapentaenoic acid (EPA) marine lipid
Docosahexaenoic acid (DHA) marine lipid

- Docosahexaenoic acid (DHA) is especially vital for the health of nerve tissues in the brain, eye and retina
- Eicosapentaenoic acid (EPA) is a direct precursor to beneficial hormone-like compounds called eicosanoids that are important regulators of vital body functions
- Play an important role as structural cell membrane lipids throughout the body
- Important function in the transport of nutrients
- Important for growth and development through their role in new tissue formation
- Important for healthy endothelial cell function
- Supports development of fetal neurological systems
- Help support healthy metabolism
- Help support cardiovascular health in combination with a healthy diet and exercise
- Help regulate the body's inflammatory processes
- Support healthy joints by helping protect joint cartilage from age-related degradation
- Help support healthy circulation
- Support healthy blood pressure already in the normal range
- Help support and maintain cholesterol levels already in the normal range
- Important for the maintenance of healthy skin
- Contribute to the maintenance of a healthy immune system
- Play an important role in providing and storing energy for the body
- Helps support and maintain already normal cholesterol levels

Certification

The undersigned certifies that the information contained in this notice is complete and accurate and that ADVOCARE International, L.P. has substantiation that the statements are truthful and not misleading.

Respectfully yours,

Sidney Stohs, Ph.D.
Senior Vice President, Research and Development
ADVOCARE International, L.P.

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